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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,301	08/10/2001	Craig A. Rosen	PA106P1	2139

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EXAMINER	
ZHOU, SHUBO	

ART UNIT	PAPER NUMBER
1631	7

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,301	ROSEN ET AL.	
	Examiner	Art Unit	
	Shubo "Joe" Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, 9-10, and 21, drawn to polynucleotides, expression vector, and host cells containing same, classified in Class 536, subclass 23.1 and 24.1; Class 435, subclasses 320.1, and 325 and 419. If this group is elected, then the below sequence election requirement also is required.

II. Claim 8, drawn to a method of making a recombinant cell using a polynucleotide, classified in Class 435, subclasses 69.1. If this group is elected, then the below sequence election requirement also is required.

III. Claims 11-12, and 16, drawn to polypeptides, classified in Class 530, subclass 300. If this group is elected, then the below sequence election requirement also is required.

IV. Claim 13, drawn to antibody, classified in Class 424, subclass 130. If this group is elected, then the below sequence election requirement also is required.

V. Claim 14, drawn to host cells expressing a particular polypeptide, classified in Class 435, subclass 325, or 419, or 252.3, or 254.11. If this group is elected, then the below sequence election requirement also is required.

VI. Claim 15, drawn to method of making a polypeptide, classified in Class 435, subclass 69.1. If this group is elected, then the below sequence election requirement also is required.

VII. Claim 17, drawn to a method of preventing, treating a medical condition using a polynucleotides, classified in Class 514, subclass 44. If this group is elected, then the below sequence election requirement also is required.

VIII. Claim 18, drawn to a method of diagnosing a pathological condition using a polynucleotide, classified in Class 435, subclass 5. If this group is elected, then the below sequence election requirement also is required.

IX. Claim 19, drawn to a method of diagnosing a pathological condition using a polypeptide, classified in Class 435, subclass 7.1. If this group is elected, then the below sequence election requirement also is required.

X. Claim 20, drawn to a method of identifying a binding partner to a polypeptide, classified in Class 436, subclass 500. If this group is elected, then the below sequence election requirement also is required.

XI. Claim 22, drawn to a method of identifying an activity in a biological assay using a polynucleotide, classified in Class 435, subclass 7.1. If this group is elected, then the below sequence election requirement also is required.

XII. Claim 23, drawn to a product that is not classifiable since its structural characteristics are not known.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups (I, II, VII-VIII, and XI), Groups (III, V, VI, IX-X), Group IV and Group XII are independent distinct inventions because they are directed to different chemical types or other subject matter regarding the critical limitations therein. For Groups (I, II, VII-VIII, and XI), the critical feature is nucleic acids; for Groups (III, V, VI, IX-X), the critical feature is a polypeptide; for Group IV, the critical feature is an antibody, and for Group XII, the critical feature is unknown except that it binds to a polypeptide. It is acknowledged that various

processing steps may cause a polypeptide of Groups (III, V, VI, IX-X) to be directed as to its synthesis by a polynucleotide of Groups (I, II, VII-VIII, and XI), however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, antibody and any chemical feature that binds to a polypeptide of the Groups supports the undue search burden if they were examined together. Additionally, polynucleotides, polypeptides, antibodies and binding partners have been most commonly, albeit not always, separately characterized and published in the biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the four Groupings of (I, II, VII-VIII, and XI), (III, V, VI, IX-X), IV and XII are independent and/or distinct invention types for restriction purposes.

The inventions of Group I and Groups II, VII-VIII, and XI are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acids of Group I can be used in the distinct processes of the inventions of Groups II, VII-VIII, and XI, i.e. making a recombinant cell (Group II), preventing (VII), diagnosis (VIII) and identifying an activity in a biological assay (XI). Alternatively, the nucleic acids of Group I can be used in antisense technologies, which is also a clearly distinct usage of such nucleic acids.

The inventions of Group I and Group V are independent products because a nucleic acid of Group I is independent of a host cell expressing a polypeptide. They have different scope,

different structure, different functions and different usages. Moreover, they are usually published separately in literature.

The inventions of Groups (III and V-VI) are related as product and distinct process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the polypeptides of Group III can be produced by distinct process of invention of Group VI using the host cells of Group V. Alternatively, the polypeptides can be produced by *in vitro* coupled transcription/translation processes.

The inventions of Group V and VI are related as product and distinct process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the host cell of Group V can be used in the distinct process of the invention of Group VI to make a polypeptide. Alternatively, the host cells can be used in making nucleic acids, etc., which is clearly a distinct usage.

The inventions of Group III and Groups (IX-X) are related as product and distinct processes of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polypeptides of Group III can be used in the distinct processes of the inventions of Group IX, which is directed to a process of diagnosing, of Group X, directed to process of identifying a binding partner.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Examination will be restricted to only the elected sequence.

This election of sequence is **NOT** a species election.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicant is further reminded that a fully responsive communication will comprise a proper election of a group and sequence as set forth above. Examination cannot proceed without a complete response.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.

Patent Examiner